K091486

510(k) Summary
Kodak 1500 Intraoral Camera

AUG 1 8 2009

1. Company Identification

Carestream Health, Inc.
150 Verona Street
Rochester, NY 14608
Establishment Registration: 1315356

2. Contact Person

Daniel Hoefer
Manager, Regulatory Affairs, Dental Systems
1765 The Exchange
Atlanta, GA 30339
Tel 770 226 3287
Fax 770 850 5011

3. Device Name

Commercial name: *Kodak 1500 Intraoral Camera*
Common name: Dental Intraoral Camera
Classification name: Dental Operative Unit

4. Device Classification

Class: I
Product Code: EIA

5. Intended Use

The *Kodak 1500 Intraoral Camera* (Kodak 1500) is intended for chairside use by dentists and dental sub-specialists during oral health examinations. It provides magnified digital color images of intraoral or extraoral anatomy via a video monitor or Personal Computer (PC). Both still and video images can be captured and stored. The device allows practitioners to view the interior of the oral cavity and assist in the assessment of the overall oral health of the patient. The Kodak 1500 also provides a tool for communicating treatment requirements or results by allowing practitioner and patient to view areas of concern together, before and after procedures.

6. Device Description

The Kodak 1500 includes a camera/handpiece assembly, docking station, and embedded acquisition software. It is available in two versions: *Kodak 1500 Intraoral Camera – wired* and *Kodak 1500 Intraoral Camera – wireless*. The wireless version, in which the handpiece transmits the acquired image data to the docking station via Wi-Fi, also includes a charging station. Users may use the

system with only a chairside video monitor, or may connect it to a PC. The camera/handpiece includes illumination via eight white-light LEDs.

7. Substantial Equivalence

The *Kodak 1500 Intraoral Camera* is substantially equivalent to Gendex AcuCam Concept IV Intraoral Camera System (Gendex, K000112) and to the STV Pro 2 (Trophy Radiologie, K033419).

- Each device is intended for use in dental or dental sub-specialty intraoral video image acquisition, for the purposes of viewing the oral cavity and patient communication.
- The technological characteristics and principles of operation are equivalent. Each device consists of a digital video camera assembled within a handpiece, connection to a docking station, and display on a chairside monitor.
- The intended users of each device are the same or similar. Each is intended for use by dentists and other oral health specialists.
- The devices are substantially equivalent in terms of energy used or delivered, materials, biocompatibility, labeling, workflow, technology, and other relevant characteristics.

8. Non-clinical Testing

Bench top performance testing of the Kodak 1500 was performed on Hardware sub-systems, Software sub-systems, and on the complete assembled device. The system also has undergone laboratory testing for mechanical, electrical, and EMC/EMI.

Results of testing demonstrate that the device is safe and effective in meeting user requirements in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Carestream Health, Incorporated
C/O Mr. Daniel Hoefer
Manager, Regulatory Affairs, Dental Systems Group
PracticeWorks Systems, LLC
1765 The Exchange
Atlanta, Georgia 30339

AUG 1 8 2009

Re: K091186
Trade/Device Name: Kodak 1500 Intraoral Camera
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Codes: EIA
Dated: July 31, 2009
Received: August 18, 2009

Dear Mr. Hoefer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091186

Device Name:
Indications for Use:

The Kodak 1500 Intraoral Camera is indicated for use by health professionals in viewing and capturing intraoral or extraoral color video images for the purposes of:

1. Allowing practitioners to view and magnify regions of the oral cavity
2. Assisting communications with the patient by providing a view of treatment areas before and after a procedure
3. Providing images for documentation in patient records.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ron Mulay for NSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091186